

### REMARKS

Claims 47-58 are pending in this application. New dependent claims 75-80 have been added herein, and no new matter is added thereby.

The Examiner's claim objections and rejections are traversed or overcome as set forth below.

#### **I. TRAVERSE OF THE ANTICIPATION REJECTION**

The Examiner rejected pending application claims 47-48, 52-54 and 58 under 35 U.S.C. 102(b) as being anticipated by "Ziehl-Neelsen stain for AFB" (1999). These claims are not anticipated because the reference teaches solvent deparaffinization and not deparaffinization with an immiscible liquid, and because the reference does not disclose every feature of the rejected claims.

##### **A. The Ziehl-Neelsen Protocol Does Not Disclose Deparaffinization With An Immiscible Liquid As Is Claimed**

Claims 47-48, 52-54 and 58 are not anticipated by the Ziehl-Neelsen protocol because the protocol does not disclose the claimed inventions to one of ordinary skill in the art. As set forth in the Declaration of Kimberly Christensen and attached to this Reply, the Ziehl-Neelsen protocol would be understood by one of ordinary skill in the art to disclose a deparaffinization technique that uses an organic solvent such as xylene. One of ordinary skill in the art would be lead to this understanding because step 2 of the protocol indicates that the sample is "taken to water". One of ordinary skill in the art would understand this step to be a rehydration step required after completion of an organic solvent dewaxing step in which an embedding medium such as wax is dissolved in the xylene solvent. (See Christensen Declaration at ¶¶ 4-6).

The claimed invention, in contrast is directed to methods that use an immiscible liquid to physically separate the embedding medium from a biological sample. (See pending independent claims 47 & 53). Since the method disclosed in the Ziehl-Neelsen protocol uses solvents and not an immiscible liquid to deparaffinize a biological sample, the reference cannot anticipate any of the pending application claims.

##### **B. The Ziehl-Neelsen Protocol Does Not Disclose Every Feature Of Claims 47-48, 52-54 And 58**

A second reason why the Ziehl-Neelsen protocol does not anticipate the claimed invention is because the protocol is silent about this requirement of claims 47-48, 42-54 and 58 of "heating the biological sample containing embedding medium to a temperature at or above the embedding medium melting point ....". The Ziehl-Neelsen protocol instructions cited by the examiner are very cursory. Taken on their face, as the examiner must, the reference does not teach any dewaxing conditions or step. The reference merely indicates that the slide is heated in a dryer to "facilitate the dewaxing". The reference does not teach that the slides are heated until the embedding medium is melted. For this reason alone, the Ziehl-Neelsen protocol does not anticipate any of the application claims.

## II. TRAVERSE OF THE OBVIOUSNESS REJECTION

The Examiner rejected claims 49-51 and 55-57 as being unpatentable under 35 U.S.C. 103(a) over the Ziehl-Neelsen protocol cited in Section I above in view of Bansbach et al. (CA 1059744 A). Claims 49-51 and 55-57 are patentable over this combination of references at least because (1) there is no suggestion for the combination of Ziehl-Neelsen with Bansbach et al.; and (2) the Ziehl-Neelsen Protocol does not disclose using water to deparaffinize biological samples.

### A. There Is No Suggestion For The Combination Of References

The Ziehl-Neelsen document is related to manipulating biological samples during sample testing protocols. Canadian Patent 1059744 A, however, is directed to a completely different area of technology - cleaning oil pipelines. There is absolutely no suggestion for the combination of Ziehl-Neelsen Protocol with Canadian Patent No. 1059744. In order to make out a *prima facie* case of obviousness, the Examiner must identify objective reasons why one of ordinary skill in the art would have been motivated to combine the references cited by the Examiner at the time of the invention. *In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988). "Combining prior art references without evidence of a suggestion, teaching, or motivation simply takes the inventors disclosure as a blueprint for piecing together the prior art to defeat patentability-the essence of hindsight." *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999).

Clearly, one of ordinary skill in the art of embedded tissue handling would not have consulted petroleum pipeline prior art in order to solve problems related to tissue testing

procedures. Since there appears to be no evidence that the examiner can point to as a suggestion for the combination of these two references, the examiner must withdraw this obviousness rejection of claims 49-51 and 55-57.

**B. The Prior Art Does Not Disclose Using An Immiscible Liquid To Separate Liquefied Embedding Medium From A Biological Sample.**

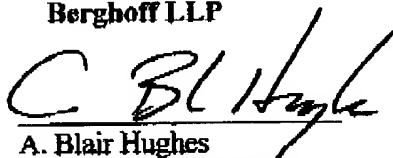
As set forth in Section I above, the prior art does not disclose the claimed invention. More specifically, the prior art does not disclose (1) heating a biological sample to a temperature at or above the embedding mediums' melting point; or (2) applying an immiscible liquid to the embedding medium to separate the liquefied embedding medium from the biological sample. Instead, as set forth in the attached Declaration of Kimberly Christensen, one of ordinary skill in the art would understand the prior art to disclose using solvents to deparaffinize a biological sample followed by rehydration of the deparaffinized sample. (See Christensen Dec. ¶¶ 4-6). For this reason as well, the examiner has failed to establish a *prima facie* case of obviousness and the rejection of claims 49-51 and 55-57 must be withdrawn.

**CONCLUSION**

In view of the amendments and statements in favor of claim patentability presented above, it is believed that all pending claims 47-58, and newly presented dependent claims 75-80 of this application are allowable and that all claim rejections and objections should be withdrawn. Favorable reconsideration and allowance of all application claims is, therefore, courteously solicited.

Respectfully submitted,

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